

REMARKS

Applicants have considered the office action mailed July 13, 2007 in connection with the above-identified patent application. Applicants thank the Examiner for acknowledging Applicants' preliminary amendment of 09/30/05, and the two information disclosure statements already of record.

Applicants note the Examiner's reminder that references identified within the application specification but not in a separate paper will not be considered by the Office. Nevertheless, Applicants are unaware of any "list" (of references) that is "incorporated into the specification" of the instant application and request that the Examiner identifies such list, if she considers part of the instant disclosure to constitute a list.

Amendments to Specification, Abstract, and Drawings

Applicants amend the specification to correct various typographical errors, for which both the nature and appropriate correction thereof would be clear to one of ordinary skill in the art, and also to replace a trademarked term by its upper-case equivalent.

The Abstract of the disclosure is amended to replace instances of "said" with "the".

Accordingly, no new matter is introduced by way of the amendments to the specification and abstract herein, and entry thereof is respectfully requested.

Drawings submitted herewith are not amended, save only for matters of form to the extent required to obtain compliance with formal requirements. No new matter is introduced herein by entering the formal drawings filed herewith.

Amendments to the Claims

Claims 1 – 9, 15, 16, 26, 29, 48, 49, and 54 – 60 are pending in the instant Application prior to entry of the instant amendments.

Claims 1, 4, 6 – 9, 15, 16, 48, 49, 56, and 60 are amended to change references to "one or more lectins" to "two or more lectins", and to make accompanying language internally consistent. Support for such an amendment can be found in the specification as filed at, for example, page 28, lines 21 – 23.

Claim 4 has been amended to insert, parenthetically, names of various lectins recited as abbreviations. Further description of these amendments to claim 4 are described herein.

Claim 5 is cancelled herein.

Claims 4, 6, and 9 are amended to correct typographical errors in references to various lectins, *e.g.*, “MAL I”, thereby also providing proper antecedent basis for recitations in subsequent claims.

Claims 29 and 54 are amended to delete the term “early-onset dental caries” from a list of dental caries, and to correct the term “DMF” to “DMFT” (see, *e.g.*, paragraph [0061] of the application as filed).

Claim 55 is amended herein to recite a component used in a Western blot (see, *e.g.*, specification as filed at page 38, line 26).

Claim 56 is cancelled herein. Claims 57 – 59 are amended to depend from claim 60.

Claim 59 is amended herein to re-write the chemical term, polyvinyl chloride without the unnecessary internal parentheses.

Applicants introduce new claims 61 – 74, each of which was originally presented in (and/or which contain material originally presented in) the international application of which the instant application is the U.S. national phase application.

Applicants also introduce new claims 75 and 76, which recite, respectively, constituents of lectin panels disclosed in Tables 1 and 2 of the specification as filed (at pages 50 and 51, respectively).

Accordingly, no new matter is introduced by way of the amendments and new claims herein, and entry thereof is respectfully requested. Applicants additionally note that each claim cancelled herein is so cancelled without prejudice to Applicants’ rights to continue to prosecute the subject matter of any of the cancelled claims in either the continued prosecution of the instant application, or in a continuing application (directly or indirectly) thereof.

INFORMALITIES

The Examiner identified two supposed defects in the specification as filed: a missing page number in the footer of the first page of the specification, and the use of a trademarked term

in uncapitalized text. Applicants have addressed the latter point by way of the amendments presented herein. Applicants are unclear as to either the consequence of the omitted page number on page 1, or how to effectively correct that omission. A substitute specification seems inappropriate in the circumstances, and the missing page number cannot be corrected via amendments to paragraphs of the specification since a page number on a specification as filed does not form part of either a published U.S. patent application or an issued U.S. patent. Applicants also question whether the omission of a page number from a specification as filed is actually an error that requires correcting. The Examiner's suggestions would be welcomed.

The Examiner further alleges both that the Abstract is missing (by not being provided on a separate sheet) and that the Abstract contains impermissible legal phraseology. Applicants also question this characterization. The international application of which the instant application is a U.S. national phase application contained an abstract upon filing (at page 80 of the disclosure and in the PCT Request). When the international application was published, the abstract appeared on the cover-page of the publication (see WO 2004/089187). The text of that abstract had been accepted as part of the instant application upon entry into the U.S. national phase (which is necessarily identical to the international application, in full) and was also published in U.S. patent application publication 2006/0263825 (the publication of the instant application).

According to MPEP §§ 608.01(b) and 1893.03(e) (emphasis added herein):

The abstract is reproduced on the cover page of the publication, even though it appears on a separate sheet of the international application in accordance with PCT Rule 11.4(a). The requirement of 37 CFR 1.52(b) that the abstract "commence on a separate physical sheet or electronic page" does not apply to the copy of the published international application communicated to the designated Offices by the International Bureau under PCT Article 20. Accordingly, *it is improper for the examiner of the U.S. national stage application to require the applicant to provide an abstract commencing on a separate sheet if the abstract does not appear on a separate sheet in the publication of the international application.*

Accordingly, Applicants disagree that the Abstract was missing from the instant application as filed. Nevertheless, Applicants provide herewith, both amendments to the abstract

as published (to replace the “legal phraseology often used in patent claims”) and an amended abstract (in clean form) on a separate sheet. Applicants believe that these, taken together, should fully address the Examiner’s objection(s).

Objections to the Claims

Regarding the Examiner’s objection to the use of certain lectin terminology within the claims, and her request to define such terms in the claims, applicants have amended claim 4 herein to insert definitions of various lectin abbreviations. The terminology used is known and understood by those of ordinary skill in the art. For example, a list of abbreviations for lectins can be found on the internet at <http://plab.ku.dk/tcbh/lectin-abbreviations.htm>, and as available from a commercial vendor, EY Labs, at

http://www.eylabs.com/index.php?option=com_content&task=view&id=74&Itemid=99, and from vendor VectorLabs at <http://www.vectorlabs.com/search.asp> by searching on a lectin abbreviation.¹ Accordingly, the instant amendments to the claims merely insert meanings of terms expanded in full and introduce no new matter.

REJECTIONS OF THE CLAIMS

Rejections under 35 U.S.C. § 112 (¶ 2)

The Examiner has rejected claims 29, 55, and 59 under 35 U.S.C. § 112 (second paragraph) as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner identified certain terms that allegedly lack definition.

The term “early-onset dental caries” in claim 29 (and also claim 54) has been deleted, thereby mooting the rejection.

The term “Western blot format” in claim 55 is objected to due to, Applicants understand, matters of form rather than because a Western blot itself would not be understood. Accordingly Applicants amend claim 55 herein to recite that the kit is configured to detect a lectin-binding component via a Western blot analysis. Such a procedure would be familiar to one of ordinary

¹ Note that, amongst different vendors it sometimes occurs that two different acronyms are used for the same lectin. Usually the difference in the acronyms is that the last letter is “A” (for agglutin) from one vendor and “L” (for lectin) from another. For example, *Datura Stramonium Lectin* can be identified as both DSL and DSA.

skill in the art, and exemplary application thereof is described in the specification at pages 32 – 33.

The parentheses objected to in claim 59 have been deleted; the name of the compound has been re-written in its more usual form.

Applicants believe that the amendments and remarks herein fully address the rejections of record under 35 U.S.C. § 112 (¶2) and respectfully request that those rejections be withdrawn.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 1 – 4, 9, 16, 26, 29, and 60 under 35 U.S.C. § 102(b) as allegedly being anticipated by Seemann *et al.*, *Caries Res.*, 35:156 – 161 (2001) (“Seemann”, hereinafter). Applicants respectfully traverse the rejection.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants respectfully point out that Seeman does not teach each and every element of Applicants’ claims.

Applicants claims, as amended herein, recite a method for predicting the risk of dental caries in a subject, based on contacting saliva from a subject with two or more lectins.

The Examiner has identified Seemann as anticipatory based on its description of a study in which the binding of salivary lycans to the single lectin PNA is measured. Since Seeman describes only studies that are based on measuring the binding of saliva components to a single lectin (PNA), and since Seemann does not describe making such measurements across a panel of lectins, such as two or more lectins, Seemann does not anticipate claims 1 – 4, 9, 16, 26, 29, and 60, as amended herein. Accordingly, Applicants respectfully request that the rejection of record be removed.

The Examiner further rejects claims 56 – 59 under 35 U.S.C. § 102(b) as allegedly anticipated by WO 97/09620 to Rylatt *et al.* (“Rylatt” hereinafter). Without acknowledging the propriety of the rejection, Applicants have cancelled claim 56 herein. Claims 57 and 59 have been amended to depend from claim 60. Accordingly, the instant amendments moot the

rejection over Rylatt and Applicants respectfully request that the Examiner acknowledge the same.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 5 –8, 15, 48, 49, 54, and 55, under 35 U.S.C. § 103(a) as allegedly being obvious over Seeman (*supra*), in view of one or more other references.

Applicants respectfully traverse the various rejections.

The framework under which obviousness of a patent claim is judged was set forth by the U.S. Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), and is as follows. Under § 103:

- the scope and content of the prior art are to be determined;
- differences between the prior art and the claims at issue are to be ascertained; and
- the level of ordinary skill in the pertinent art resolved.

Based upon the answers to these factual enquiries, the obviousness or nonobviousness of the claimed subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might also be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Accordingly, and at a minimum, in order to establish obviousness of a claim, the prior art reference, or references when combined, must teach or suggest each and every limitation of the claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Furthermore, and in instances where each and every limitation of the claimed invention can be found in a combination of references, an analysis of an apparent reason to combine the known elements in the fashion claimed should be made explicit. *KSR Int'l. Co. v. Teleflex Inc.*, (04-1350, U.S. S.Ct., April 30, 2007).

Applicants begin with the last of the articulated rejections under 35 U.S.C. § 103, in order to emphasize certain core aspects of their arguments common to several of the rejections of record.

Claims 5, 6, 7, 8, and 48

The Examiner has rejected claims 5, 6, 7, 8, and 48 under 35 U.S.C. § 103(a) as allegedly being obvious over Seeman (*supra*), in view of U.S. Patent No. 4,582,795 to Shibuya *et al.*, (“Shibuya”)² and further in view of Sharon, *Adv. Exp. Med. Biol.*, 408:1 – 8 (1996) (“Sharon”). In the Examiner’s view, although Seeman only discloses a test that uses a single lectin (PNA), since Sharon discloses a number of carbohydrate-lectin binding interactions, Applicants claims that recite use of various other lectins would have been obvious. Claim 5 is cancelled herein; Applicants rebut the rejection of the remaining claims as follows.

Applicants respectfully traverse this rejection because, as discussed hereinabove, Seeman does not disclose testing for multiple (*i.e.*, two or more) lectins but instead discloses tests based on just one (in particular, PNA). Furthermore, and notwithstanding knowledge in the art (such as provided by Sharon) of the existence of numerous other lectins, Seeman has clearly shown that other lectins were not likely to be suitable in diagnostic methods, and in particular has provided no indication that choices of two or more lectins would be likely to succeed. For instance, Seeman at p.158 (l.h. col.) references several purified plant and animal lectins that were used (BSA, VVA, WGA, ConA, GNA, and AAL). However, further down that same page (r.h. col.) he notes that: “[t]here was no difference in the binding inhibition activity for the other lectins used in this study.” Thus, there is nothing in Seeman to imply or teach that if one takes lectins that do not individually and significantly relate to caries risk, and now group them, the result will be magically transformed into a relationship that is an accurate assessment of an individual’s caries risk. Sharon does not address this central deficiency, at least because Sharon makes no mention of using lectins for diagnostic purposes.

Finally, Applicants respectfully point out that the relationship of claims 5 – 8 to the cited references is as species (specific lectins or groups of lectins) to genus (lectins as a whole). A genus in the prior art cannot anticipate or render obvious claimed species without specific disclosure or teachings that call out the later claimed species. Since neither of the cited

² Applicants believe that the Examiner’s reliance on Shubiya in formulating this rejection is misplaced, and possibly as a result of a clerical error. Therefore, Applicants do not address Shubiya when rebutting this rejection.

references calls out the groups of lectins recited in the claims, either in whole or in part, the claims cannot be said to be obvious over those references.

Accordingly, Applicants respectfully submit that claims 5, 6, 7, 8, and 48 are not obvious over the cited references and request that the rejection be withdrawn.

Claims 49, 54, and 55

The Examiner has rejected claims 49, 54, and 55, under 35 U.S.C. § 103(a) as allegedly being obvious over Seeman (*supra*), in view of U.S. Patent No. 4,444,879 to Foster *et al.*, (“Foster”) because, although Seeman does not disclose a kit form for measuring lectin-binding components, kits of various forms are known in the art, *e.g.*, Foster.

Applicants respectfully traverse this rejection because, as discussed hereinabove, Seeman does not disclose testing for multiple (*i.e.*, two or more) lectins but instead discloses use of just one (*e.g.*, PNA). Foster does not provide for kits that test for any number of lectins. Therefore, regardless of whether kit forms for testing reagents are known in the art, the fact that neither Seeman nor Foster discloses methods or kits for testing based on multiple lectins means that claims 49, 54, and 55 as amended herein are not obvious over the combination of references.

Claim 15

The Examiner has rejected claim 15 under 35 U.S.C. § 103(a) as allegedly being obvious over Seeman (*supra*), in view of U.S. Patent No. 4,582,795 to Shibuya *et al.*, (“Shibuya”) because, although Seeman does not disclose measurement of a drop of saliva in a matrix material, Shibuya discloses a method and device for rapid diagnosis of dental caries that utilizes a very small amount of saliva.

Applicants respectfully traverse this rejection because, as discussed hereinabove, Seeman does not disclose testing for multiple (*i.e.*, two or more) lectins but instead discloses just one (*e.g.*, PNA). Shibuya does not refer to lectins at all. Therefore, regardless of the manner in which Shibuya describes testing for saliva, the fact that neither Seeman nor Shibuya discloses methods for testing based on multiple lectins means that claim 15 as amended herein is not obvious over the combination of references.

Applicant : Denny, et al.
Serial No. : 10/551,612
Filed : July 26, 2006 (§ 371(c)(1,2,4) date)
Page : 20 of 21

Attorney Docket No.: 19644-005US1

Accordingly, none of the rejected claims is obvious over the cited references, and Applicants respectfully request removal of the rejection.

CONCLUSION

In view of the above remarks, Applicants respectfully submit that the subject application is in good and proper order to proceed to issue. If, in the opinion of the Examiner, a telephone conference would resolve any outstanding matters not heretofore resolved, the Examiner is encouraged to call the undersigned at (650) 839-5070.

No fee is believed owed in connection with filing of this amendment. Nevertheless, should the Commissioner determine otherwise, he is authorized to charge any underpayment or credit any overpayment to Applicant's Deposit Account No. 06-1050 (Ref. 19644-005US1) for any charges or credits.

Respectfully submitted,

Date: January 14, 2008

Richard G. A. Bone

Richard G. A. Bone
Reg. No. 56,637

Fish & Richardson P.C.
500 Arguello Street, Suite 500
Redwood City, California 94063
Telephone: (650) 839-5070
Facsimile: (650) 839-5071